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ATTORNEY FOR PLAINTIFF
UNITED STATES OF AMERICA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION

UNITED STATES OF AMERICA, **Plaintiff,** **vs.** **SHERRY GAIRRETT,** **Defendant.**	**CV 22-106-GF-BMM-JTJ** **COMPLAINT**

The United States of America, on behalf of its agency the Drug Enforcement Administration ("DEA"), alleges as follows:

I. NATURE OF ACTION

1. The United States of America brings this civil enforcement action against Sherry Gairrett, APRN, seeking penalties and injunctive relief for violations of Title II of the Comprehensive Drug Abuse Prevention and Control

Act of 1970 (the "Controlled Substances Act" or "CSA"), 21 U.S.C. § 801 et seq., as amended, and its implementing regulations, 21 C.F.R. § 1301 et seq. (the "CSA regulations").

2. As a practitioner who dispenses or administers controlled substances, Sherry Gairrett assumed critical gatekeeping responsibilities under the CSA to comply with the CSA's recordkeeping and prescribing requirements, which Congress enacted to prevent the diversion of controlled substances for illegal purposes.

3. Between November of 2017 and September of 2021, Sherry Gairrett issued numerous prescriptions for Schedule II controlled substances – specifically oxycodone and hydrocodone – to multiple patients that were outside the usual course of medical practice and not for a legitimate medical purpose.

II. THE PARTIES

4. Plaintiff is the United States of America, acting through the United States Department of Justice, Drug Enforcement Administration, and its agent employees.

5. Defendant Sherry Gairrett ("Gairrett") is a board-certified Family Nurse Practitioner and an Advanced Practice Registered Nurse in the State of Montana, license # NUR-APRN-LIC-100720. At all times pertinent to this action

Gairrett has been registered with the DEA to prescribe controlled substances, with registration # MG2562533. Gairrett currently works at Northern Montana Health Care in Havre, Montana.

III. JURISDICTION AND VENUE

6. This Court has jurisdiction under 28 U.S.C. §§ 1345 (United States as Plaintiff), 1355 (Fine, penalty or forfeiture), 2201 (the Declaratory Judgment Act) and, insofar as construction of federal law is concerned, 1331 (federal question).

7. A justiciable controversy exists between Plaintiff and Defendant, and the relief requested by Plaintiff is proper pursuant to 28 U.S.C. §§ 2201-2202, and Rule 65 of the Federal Rules of Civil Procedure.

8. Venue is proper under 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b) and 1395(a) in the Great Falls Division of the District of Montana because the acts and omissions complained of occurred in Phillips County and Daniels County, Montana, and Gairrett currently works and resides in Hill County, Montana.

IV. FACTS

THE CONTROLLED SUBSTANCES ACT

9. Congress enacted the CSA because it determined that the "illegal importation, manufacture, distribution, and possession and improper use of

controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801.

10. The CSA classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories, called schedules, depending on the drug's acceptable medical use and the drug's abuse or dependency potential.

11. Schedule II contains drugs found to have "a high potential for abuse" that "may lead to severe psychological or physical dependence" but nonetheless have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2). Schedule IV drugs have a "low[er] potential for abuse," but abuse may still "lead to limited physical dependence or psychological dependence." 21 U.S.C. § 812(b)(4).

12. As relevant here, oxycodone and hydrocodone are regulated as Schedule II controlled substances under the CSA. Carisoprodol and lorazepam are regulated as Schedule IV controlled substances under the CSA.

13. For Schedule II-V drugs, the CSA creates a comprehensive, closed regulatory system for dispensing, distributing, and possessing controlled substances. This comprehensive system tracks and traces controlled substances from manufacture to delivery to ensure they are not illegally diverted for improper uses. Each participant in the closed system for authorized distribution of

controlled substances maintains a registration with the DEA that authorizes their professional access to controlled substances.

14. At each step in the process – from manufacture to prescription to ultimate delivery – DEA registrants have specific obligations designed to ensure that controlled substances are not diverted from the legitimate chain of distribution.

CSA Prescribing Violations

15. The CSA makes it unlawful to "dispense" controlled substances without a valid prescription. 21 U.S.C. § 842(a)(1); 21 U.S.C. § 829; 21 C.F.R. § 1306.04(a). Under the CSA, issuing a prescription is a form of dispensing. 21 U.S.C. § 802(10). As such, a prescription for a controlled substance is invalid unless it complies with the CSA and CSA regulations.

16. Among other requirements, a valid prescription must be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). "An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent" of 21 U.S.C. § 829, and "the person issuing it shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id*.

17. The prescribing practitioner is responsible for the proper prescribing and dispensing of controlled substances. 21 C.F.R. § 1306.04(a).

18. Whether a prescription is issued for a legitimate medical purpose and consistent with the usual course of professional practice is determined based on generally accepted objective medical standards.

19. Each prescribing violation is subject to a civil penalty. The maximum penalty for violations occurring after November 2, 2015, is $72,683. 21 U.S.C. § 842(c)(1)(B), as adjusted by Section 701 of the Bipartisan Budget Act of 2015, Public Law 114-74 (Nov. 2, 2015); 28 C.F.R. § 85.5.

Medical Standard for Opioid Prescribing

20. Pain management patient care has evolved as knowledge of the opioid crisis has grown. The lowest effective dose of opioids is always preferred, with caution advised for dosages above 50 morphine milligram equivalent per day ("MME") and careful justification for doses above 90 MME.

21. Additional practices have become standard medical procedure to prevent opioid addiction and abuse, such as entering pain agreements/contracts, urine drug testing, pill counts, follow-up appointments, and limitations on early refills. Periodic assessment of each patient's pain and the suitability of both pharmacological and non-pharmacological therapies is recommended.

22. In 2016, the Center for Disease Control published a Guideline for Prescribing Opioids for Chronic Pain. Among its recommendations, the CDC guidelines included:

a. Medical providers should consider prescribing opioids "only if expected benefits for both pain and function are anticipated to outweigh the risks to the patient." In addition, "if opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate."

b. Before starting opioid therapy, medical providers should review the risks of opioids with the patient and set treatment goals. Those goals and the risk of opioids should be periodically reviewed with the patient.

c. Medical providers should prescribe the lowest effective dosage of opioids, should "avoid increasing" dosages to 90 MME per day, and should "carefully justify" any dosages of 90 MME per day (or more).

d. Medical providers should use urine drug screening before prescribing opioids, and should use urine drug screening "at least annually" to assess for prescribed medications as well as other prescribed or unprescribed drugs.

e. Medical providers "should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible."

Gairrett's Prescribing

23. Gairrett worked at Phillips County Hospital in Malta, Montana, from April of 2007 to August of 2018. Gairrett then worked at Daniels Memorial Healthcare Center in Scobey, Montana, from September of 2018 through at least September 2021.

24. As relevant here, at least four of Gairrett's pain management patients continued to see Gairrett even after she moved from Phillips County Hospital in Malta to Daniels Memorial in Scobey. Gairrett continued to prescribe opioids and other controlled substances to these patients until roughly September of 2021. Gairrett was interviewed by DEA investigators about her prescribing practices on July 27, 2021, and shortly after that time Gairrett essentially stopped prescribing opioids to pain management patients.

25. Both Phillips County Hospital and Daniels Memorial Healthcare Center had pain management practices in place during the relevant time frame. However, Gairrett did not follow those standard procedures for at least four patients. There is also little to no documentation that Gairrett validated pain

measurements, pain descriptions, or discussed non-pharmacological therapy for any of these four patients.

26. Gairrett issued opioid prescriptions to Patient 1 from at least March 2017 through September 2021. Gairrett regularly issued concurrent oxycodone (instant-release) and oxycontin (extended-release) opioid prescriptions to Patient 1 with resulting dosages exceeding 150 MME. Gairrett also regularly prescribed Patient 1 carisoprodol, a muscle relaxant which is a known opioid potentiator. In 2018, Gairrett changed Patient 1's opioid prescriptions to just the instant-release oxycodone, and increased the dosage to 270 MME per day. In total, it is believed that Gairrett issued at least 76 prescriptions for controlled substances to Patient 1 between November 1, 2017, and the present.

27. Gairrett issued those prescriptions to Patient 1 despite numerous red flags, including:

a. Prescribing any opioids to Patient 1 was against the express, written advice of Dr. Edwin Medina, the Chief Medical Officer of Philips County Memorial Hospital.

b. There was no documented pain agreement between Gairrett and Patient 1.

c. Patient 1 was prescribed additional pain medications because of tooth pain, with no mention of high levels of opioids already given for ostensible pain management.

d. Patient 1 frequently tried to fill opioid prescriptions early, resulting in refusal by multiple pharmacies to handle Patient 1's prescriptions at all.

e. There is documentation of only one urine drug screening in the four years Gairrett prescribed to Patient 1.

28. Since Gairrett stopped prescribing to Patient 1, another medical provider has reduced Patient 1's opioid prescriptions to 90 MME per day, which is one-third of the strength and quantity Gairrett prescribed.

29. Gairrett issued oxycodone and hydrocodone prescriptions to Patient 2 from at least March 2017 through July 2021. Gairrett regularly issued hydrocodone prescriptions with dosages of 80 MME. Gairrett also regularly prescribed Patient 2 lorazepam, a benzodiazepine which is a known opioid potentiator. In total, it is believed that Gairrett issued at least 49 prescriptions for controlled substances to Patient 2 between November 1, 2017, and the present.

30. Gairrett issued those prescriptions to Patient 2 despite numerous red flags, including:

a. Patient 2's health insurer denied Gairrett's prescription for 180 hydrocodone per month, stating the most they would authorize was 120.

b. Patient 2 refused an MRI of her right shoulder, the reason for Gairrett's opioid prescriptions.

c. Patient 2 had chronic allergy and sinus issues, and frequently reported taking Ibuprofen and Tylenol, on top of the hydrocodone she was ostensibly taking.

d. In 2019 Patient 2 travelled to Scobey to be seen by Gairrett and receive her prescriptions, but Patient 2 continued to go to Phillips County Memorial Hospital in Malta for other medical issues.

e. In November of 2019, Patient 2's urine drug screening was negative for any opiates in her system, which is a red flag for potential diversion of the prescribed controlled substances. Gairrett continued prescribing opioids to Patient 2 without any documentation in the medical records of any response to the negative drug screening.

31. Since Gairrett stopped prescribing opioids in July 2021, Patient 2 has not received opioid prescriptions from any other medical provider in Montana.

32. Gairrett issued oxycodone and hydrocodone prescriptions to Patient 3 from at least February 2017 through August 2021. Gairrett regularly issued

hydrocodone prescriptions to Patient 3 resulting in 80 MME per day. In addition, Gairrett also regularly prescribed Patient 3 lorazepam, a benzodiazepine and known opioid potentiator. In total, it is believed that Gairrett issued at least 71 prescriptions for controlled substances to Patient 3 between November 1, 2017, and the present.

33. Gairrett issued those prescriptions despite numerous red flags, including:

a. In June 2017, Patient 3 received hydrocodone from a different provider in addition to Gairrett's prescriptions, which was a violation of Patient 3's pain contract.

b. In July 2017, Patient 3 had a urine drug screening that was negative for opioids but positive for cannabis, another pain contract violation.

c. In September 2017, Patient 3 called and sated that she mislaid her hydrocodone prescription. Gairrett issued a new prescription and mailed it to Patient 3 in another state.

d. In January 2018, Patient 3's urine drug screening was again missing any opioids, but was instead positive for amphetamines.

e. In August 2018, Patient 3 wanted the opioid prescriptions filled early, ostensibly because she was going on a trip.

34. Gairrett issued opioid prescriptions to Patient 4 from at least January 2017 to August 2021. Gairrett regularly issued a combination of oxycontin and hydrocodone prescriptions with a combined dosage of 100 MME per day. In addition, Gairrett also regularly prescribed Patient 4 lorazepam, a benzodiazepine and known opioid potentiator. In total, it is believed that Gairrett issued at least 43 prescriptions for controlled substances to Patient 4 between November 1, 2017, and the present.

35. Gairrett issued those prescriptions despite numerous red flags, including:

a. In September 2018, Patient 4's urine drug screening was negative for opiates.

b. In 2019 Patient 4 travelled to Scobey to be seen by Gairrett and receive her prescriptions, but Patient 4 continued to go to Phillips County Memorial Hospital in Malta for other medical issues.

36. Since March 2022, Patient 4 has been treated by another medical provider for opioid addiction, not pain management.

37. In addition to these individual concerns, the medical records for each of Patients 1-4 consistently show that Gairrett:

a. did not attempt to address the root causes of the patient's ostensible pain with non-opioid modalities;

b. did not properly use pain contracts, urine drug screenings, pill counts, or other common methods to prevent misuse or diversion of opioids; and

c. did not properly justify her opioid and other controlled substance prescriptions.

V. CLAIMS FOR RELIEF

COUNT I

Unlawful Prescribing of Controlled Substances: 21 U.S.C. §§ 829, 842(A)(1)

(Civil Penalties: 21 U.S.C. § 842)

38. The United States incorporates by reference paragraphs 1 through 37 above as if set forth in full here.

39. 21 U.S.C. § 842(a)(1) makes it unlawful to for any person subject to Part C of the CSA to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829. Gairrett is subject to Part C and has been at all times relevant to the allegations in this Complaint.

40. For at least four patients and over the course of several years, Gairrett dispensed controlled substances by issuing purportedly valid prescriptions, but which were not issued for a legitimate medical purpose by a practitioner acting in the usual course of her professional practice, in violation of 21 U.S.C. § 829. *See* 21 C.F.R. §§ 1306.01, 1306.04(a). The total number of violations will be proven at trial, but is believed to be at least 239 separate, invalid prescriptions for controlled substances.

41. In so doing, Gairrett dispensed these controlled substances in violation of 21 U.S.C. §§ 829(a), 842(a)(1), and 21 C.F.R. § 1306.04.

42. Under 21 U.S.C. § 842(c)(1)(A), as adjusted by 28 C.F.R. § 85.5 pursuant to PL 114-74 § 701, each of these dispensing violations subjects Gairrett to a civil penalty of not more than $72,683.00 per violation.

COUNT II

Unlawful Prescribing of Controlled Substances: 21 U.S.C. §§ 829, 842(a)(1)

(Injunctive Relief: 21 U.S.C. §§ 843, 882)

43. The United States repeats and realleges Paragraphs 1 through 37 as if set forth in full here.

44. As a result of the violations set forth above, the United States is entitled to injunctive relief against Gairrett pursuant to 21 U.S.C. §§ 843(f) and 882(a).

VI. REQUEST FOR RELIEF

WHEREFORE, the United States requests judgment in its favor and against Defendant Sherry Gairrett as follows:

A. for Count 1, impose the maximum civil penalty for each and every illegal prescription issued in violation of 21 U.S.C. §§ 829 and 842(a)(1);

B. for Count 2, enjoin Sherry Gairrett from issuing prescriptions for controlled substances for a period no less than five years;

C. for interest, attorneys' fees, and costs as allowed by law; and

D. for all such further relief as the Court may deem just and proper.

DATED this 8th day of November, 2022.

JESSE A. LASLOVICH
United States Attorney

/s/ Michael A. Kakuk
Assistant U. S. Attorney
Attorney for Plaintiff